

Remarks

The Office Action mailed July 18, 2003 has been received and reviewed. Claims 30 and 37 having been amended and claims 1-8 and 22-29 having been canceled, the pending claims are claims 9-21 and 30-71. Reconsideration and withdrawal of the rejections are respectfully requested.

The amendment of claim 30 is supported by claim 30 as originally filed, and by the specification at, for instance, the paragraph spanning pages 28 and 29.

The amendment of claim 37 to recite "a companion animal" is supported by the specification at page 22, lines 2-16.

Restriction Requirement

Applicants have elected Group V (claims 30-38) and the species *Salmonella* spp.

Pursuant to MPEP 809.02(a), the following is a listing of all claims readable on the elected species: claims 30-38. However, at item 2 of the Action (page 2), the Office notes that claims 31-33 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b). It is Applicants' position that claims 31-33 are generic to the elected species. The Office is requested to reconsider the withdrawal of claims 31-33 and reinstate those claims.

It is understood that the generic claims will be examined fully with respect to the elected species and that, if no prior art is found that anticipates or renders obvious the elected species, the search will be extended to the extent necessary to determine the patentability of the generic claims. Upon allowance of a generic claim, it is further understood that Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claims as provided by 37 C.F.R. 1.141.

Title of the Invention

As requested by the Examiner, the title of the invention has been amended to "METHODS FOR REDUCING SHEDDING OF A MICROBE BY AN ANIMAL."

Objections to the Disclosure

The Office objected to the disclosure for containing an embedded hyperlink and/or other form of browser-executable code. Applicants respectfully disagree; however, in the interests of furthering prosecution, the disclosure has been amended at the paragraph beginning at page 14, line 7, to remove the term www.animal.ufl.edu/short94/rae.htm and replace it with animal.ufl.edu/short94/rae.htm

The Office also objected to the disclosure for inclusion of a misspelled word at the paragraph beginning at page 14, line 7. The typographical error has been corrected.

The Office is requested to reconsider and withdraw the objections to the disclosure.

Information Disclosure Statement

Information Disclosure Statement mailed August 26, 2002

Applicants also submitted an Information Disclosure Statement on August 26, 2002; however, not all the documents cited in the Information Disclosure Statement were matched with the file. Applicants note with appreciation that the Examiner will consider those documents that were not initialed on the 1449 forms. A duplicate copy of each of those documents is submitted herewith.

Information Disclosure Statement mailed June 27, 2003

Applicants submitted an Information Disclosure Statement on June 27, 2003, which cited 6 documents. A copy of the 1449 form included with the Information Disclosure Statement, marked as being considered and initialed by the Examiner, was not present with the Action mailed July 18, 2003.

Consideration of each of the documents listed on the 1449 form(s) mailed August 26, 2002, and June 27, 2003, is respectfully requested. Pursuant to the provisions of MPEP §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

The 35 U.S.C. §102 Rejection

Claims 30 and 34-38 are rejected under 35 U.S.C. §102 as being anticipated by Emery et al. (WO 95/21627) in light of Lumsden et al., Am. J. Vet. Res., 52, 1784-1787 (1991). This rejection is respectfully traversed.

The Action states that "[a]lthough the prior art is silent with regard to LPS [the] claim recites that the composition has a concentration no greater than 10 EU/ml, therefore a composition that has no LPS would meet that limitation." Applicants agree that Emery et al. is silent regarding the concentration of LPS. Although it was not made explicit, it appears that this rejection is based on the doctrine of inherency. Specifically, it appears that this rejection is based on the allegedly inherent properties of the compositions of Emery et al. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P §2112 (emphasis in original). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P §2112 (emphasis in original). It is respectfully submitted that the Examiner has not met her burden of providing a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the cited documents.

Emery et al. disclose compositions for vaccinating animals against, for instance, infection by gram-negative bacteria. Emery et al. disclose at page 46, lines 29-36, that intestinal shedding of Salmonella was detected in non-vaccinated birds and not detected in vaccinated birds. The authors further suggest that the proteins taught in the document may have some beneficial effect in preventing the intestinal colonization of Salmonella. Emery et al. do not teach that the compositions that were administered to animals had a concentration of LPS of no greater than about 10.0 EU/ml. In contrast, independent claim 30 recites administering to an animal an effective amount of a composition comprising, inter alia, LPS at a concentration of no greater than about 10.0 EU/ml. Emery et al. do not expressly disclose that an effective amount

of a composition contains LPS at a concentration of no greater than about 10 EU/ml, thus Emery et al. do not anticipate the claimed invention.

The Office is respectfully requested to reconsider and withdraw the rejection of the pending claims over the cited art.

Double Patenting Rejection

Claims 30 and 34-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,830,479 in view of Lumsden et al. or claims 1-16 of U.S. Patent No. 6,027,736 in view of Lumsden et al. This rejection is respectfully traversed.

"Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent (M.P.E.P §804 (II)(B)(1), emphasis in original). "A double patenting rejection of the obviousness-type is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103' except that the patent principally underlying the double patenting rejection is not considered prior art. Therefore, any analysis employed in an obvious-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination" (M.P.E.P §804(II)(B)(1)).

The present claims are patentably distinct from the subject matter claimed in the two cited patents. Further, claims 1-16 of U.S. Patent No. 5,830,479 and claims 1-16 of U.S. Patent No. 6,027,736 do not teach or suggest the subject matter of the pending claims of the present application. "The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." M.P.E.P. §706.02(k) (emphasis added). It is respectfully submitted

that claims 1-16 of U.S. Patent No. 5,830,479 and claims 1-16 of U.S. Patent No. 6,027,736 do not suggest the claimed invention, and no convincing line of reasoning has been presented.

The Office is respectfully requested to reconsider and withdraw the rejection of the pending claims under the doctrine of obviousness-type double patenting over claims 1-16 of U.S. Patent No. 5,830,479 and claims 1-16 of U.S. Patent No. 6,027,736.

Provisional Rejection under 35 U.S.C. 101

Claims 30 and 34-38 are provisionally rejected as claiming the same invention as claims 30 and 34-38 of copending U.S. Application No. 20030036639. This rejection is respectfully traversed.

U.S. Application No. 20030036639 is the published application that corresponds to the present application. Both the published application and the present application have the same serial number, 10/038,504, and were filed on the same day, January 3, 2002. The Office is requested to reconsider and withdraw this provisional rejection.

Amendment and Response

Serial No.: 10/038,504

Confirmation No.: 5492

Filed: January 3, 2002

For: IMMUNIZING COMPOSITIONS AND METHODS OF USE

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Summary

It is respectfully submitted that the pending claims 30-37 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Emery et al.

By
Muetting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

Oct. 20, 2003
Date

By: David L. Provence
David L. Provence
Reg. No. 43,022
Direct Dial (612)305-1005

CERTIFICATE UNDER 37 CFR §1.10:

"Express Mail" mailing label number: **EV 073687948 US**

Date of Deposit: **OCTOBER 20, 2003**

The undersigned hereby certifies that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Sam Her
Name: **SAM HER**
